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LabLink

this issue

Director, Bureau of Laboratories, Sandip Shah, Ph.D., HCLD(ABB)

Important Reminders for 2016!

BOL test requisition and form completion:
Remember to enter the **correct year** on all laboratory test requisitions and forms. Please double check the date of collection. Also remember to double check the date of birth for newborn screening sample requisitions.
Incorrect submission data is a common oversight, especially in January, and is a major pre-analytic error that results in unexpected delays for specimen analysis and test results reports.

Please visit our web page at:
http://www.michigan.gov/mdhhslab
Reminder! Our public email box is:
mdhhslab@michigan.gov

Bureau Vision:
The Bureau of Laboratories is a stronger, more diverse team within an integrated public health system. We utilize advanced technology and innovative leadership to provide comprehensive public health services in our dynamic global community.

Bureau Mission:
We are dedicated to continuing leadership in providing quality laboratory science for healthier people and communities through partnerships, communication and technical innovation.

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MDHHS
Michigan Department of Health & Human Services
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Mycobacterium tuberculosis complex-*Mycobacterium avium* complex Polymerase Chain Reaction

Author: Laurel L. Vibber, MS, Microbiologist, Mycobacteriology Unit

Tuberculosis disease continues to be a public health concern. The emergence of drug resistant *Mycobacterium tuberculosis* (MTB) is making early diagnosis and treatment more important than ever. Risk factors that make one more susceptible to tuberculosis include HIV infection, persons born outside of the United States, health care workers, and diabetes mellitus. Early diagnosis can prevent the spread of infection and reduce the duration and severity of disease.

The Michigan Department of Health and Human Services (MDHHS) will be offering a new Nucleic acid amplification test (NAAT) to replace the current *Mycobacterium tuberculosis* complex Direct (MTD) test. The new methodology employs real-time polymerase chain reaction (PCR) and will include the detection of *Mycobacterium avium* complex (MAC) in addition to *M. tuberculosis* complex (MTBC). The real-time PCR assay does not differentiate among members of the *M. tuberculosis* complex (*M. tuberculosis, M. bovis, M. bovis BCG, M. africanum, M. microti, and M. canettii)* or members of the *M. avium* complex (*M. avium, M. avium subsp. avium, M. avium subsp. paratuberculosis, M. intracellulare, M. chimaera, M. arosiense, M. colombiense, M. marseillense, M. bouchedurhonense, and M. timonense).*

Real-time PCR uses the presence of a fluorescent labeled probe along with forward and reverse primers. An increase in DNA during PCR increases fluorescence from the probe. The fluorescence is measured in each PCR cycle, resulting in a sigmoidal curve in the presence of *M. tuberculosis* complex DNA or *M. avium* complex DNA. Different probe dyes are used to detect each organism so both targets can be detected in the same tube. This assay uses two probe and primer sets to detect the presence of MTBC. The first probe and primer set targets the *IS6110* region that is present in most members of the MTBC in multiple copies. The second probe and primer set was added to detect the few strains in the MTBC that do not have *IS6110*. Due to the genetic diversity of the MAC members, several primers are pooled together to make the working primer for this assay. This type of PCR is called a multiplex reaction and is used to save time and cost.

NAAT will be performed on new smear positive respiratory specimens from sputum, bronchial washes, and tracheal aspirates. Currently the test is not validated for non-respiratory specimens. Testing will be provided on smear negative specimens only when there is a positive skin test or Interferon-gamma release assay (IGRA), positive chest x-ray, or contact to a known tuberculosis disease case. Prior approval is needed for smear negative testing. The sensitivity of the test is lower when testing smear negative specimens.

This test was developed by MDHHS and is not an FDA approved test. The sensitivity for MTBC is 98.7% and the specificity is 96.6%. The sensitivity for MAC is 77.1% and the specificity is 100%. Molecular testing needs to be used in conjunction with clinical findings. A positive PCR result indicates the presence of MTBC and/or MAC DNA. This does not necessarily indicate active clinical disease. A positive result may also occur if there are non-viable organisms or residual cellular DNA in the sample.

The limit of detections for *Mycobacterium tuberculosis* complex and *Mycobacterium avium* complex calculated for this assay may NOT detect DNA present in low quantities; therefore, false negatives may occur.

Test results may be affected by specimen collection, transport, and sampling variability. A negative test does not exclude the possibility of isolating *M. tuberculosis* complex or *M. avium* complex from the specimen.

Michigan Department of Health and Human Services Newborn Screening Program to Implement HL7 Messages-Receives APHL NewSTEPs 360 Grant Award

Author: Heather Wood, MS, Scientist, Newborn Screening Section

The Michigan Department of Health and Human Services newborn screening program was one of 20 states selected to receive funding from the Newborn Screening Technical assistance and Evaluation Program (NewSTEPs 360). The NewSTEPs 360 program is collaboration between the Colorado School of Public Health and the Association of Public Health Laboratories (APHL). Michigan Department of Health and Human Services newborn screening (MDHHS NBS) program will receive $120,000 of funding over a three year period from September 2015 to September 2018. The primary focus of the NewSTEPs 360 program is to improve timeliness of newborn screening (NBS).

The Secretary's Advisory Committee on Heritable Diseases in Newborns and Children has made recommendations for timely reporting that include reporting all NBS results within seven days of life with the time critical conditions being reported no later than the fifth day of life. From the birth of the baby to the NBS results being reported, there are several checkpoints that could be used to measure quality indicators for the timeliness of the NBS process. These checkpoints include collection of the specimen with proper data recording, delivering the specimen within the hospital to the courier pickup site, courier delivery of specimen to the MDHHS NBS laboratory, NBS for collected specimens, and NBS results reporting to the submitting hospital, provider, or parent. MDHHS NBS laboratory, focus is to improve NBS turnaround time (TAT) through process improvements involving specimen collection recording and the NBS results reporting to the submitter. Hospitals currently receive critical results by phone and negative results by fax or hard copy mail. The TAT is conventionally considered in the context of the laboratories' ability to quickly return a lab report to a hospital; however, with the inception of HL7 messaging, hospitals will have the opportunity to experience a reduction in the amount of time required for results to be applied to a newborn's medical record.

Eight Michigan hospital systems were identified via an online survey as having high interest in development of HL7 messaging capability for submission of NBS test orders and receipt of specimen results. Through this grant, MDHHS NBS program will provide financial incentive for each hospital system that has agreed to employ Health Information Technology for electronic submission of NBS demographic data, test orders, and Critical Congenital Heart Disease test results to the MDHHS NBS laboratory. By working with the eight Michigan hospital systems with onboarding HL7 messaging, the MDHHS NBS program goal is to monitor and improve the following quality indicators: proper data field recording for test orders, decrease time between specimen collection and specimen receipt to the MDHHS NBS laboratory, and a decrease in time for NBS results reporting to the submitting hospital, provider, or parent.

This grant provides the means to reduce TAT for both specimen submission and result reporting from the capability of the MDHHS NBS laboratory and hospital systems to track the number of tests and production HL7 messages sent and received (tracked by hospital and date), time between specimen collection and specimen receipt by the MDHHS NBS laboratory, the number of HL7 specimen receipt messages, the number of result messages successfully received by hospital systems, and the percent reduction in data entry errors on the MDHHS NBS laboratory daily supervisory review report, and a decrease in required data entry time.

MEDDRUN, CHEMPACK, and SNS Online Course

Author: Kerry Chamberlain, PhD, MPH, Outreach, Evaluation, and Exercise Liaison, Division of Emergency Preparedness and Response, Bureau of EMS, Trauma, and Preparedness

The Bureau of EMS, Trauma and Preparedness created an online learning course to familiarize learners with Michigan's **Michigan Emergency Drug Delivery Resource Utilization Network** (MEDDRUN), CHEMPACK and Strategic National Stockpile (SNS) programs. This module is a self-study and takes about an hour to complete. Continuing education credits are available for physicians, nurses, pharmacists, and EMS.

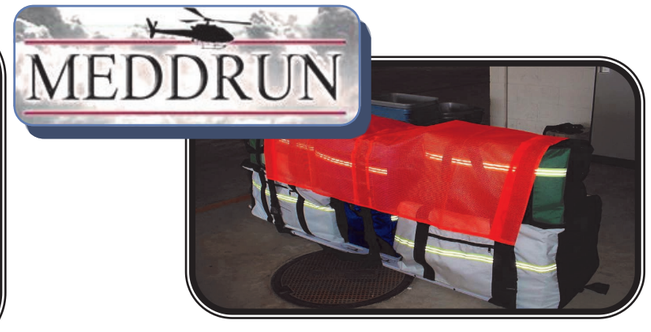
During the early phases of a mass casualty incident, particularly an event due to a terrorist attack using a chemical agent, healthcare systems will likely be overwhelmed. It is likely that critical emergency pharmaceuticals and other vital medical supplies may be compromised or locally limited. Two standardized pharmaceutical caches, MEDDRUN and CHEMPACK, are available to support healthcare agencies to bridge the gap between the local, regional, and state resources.

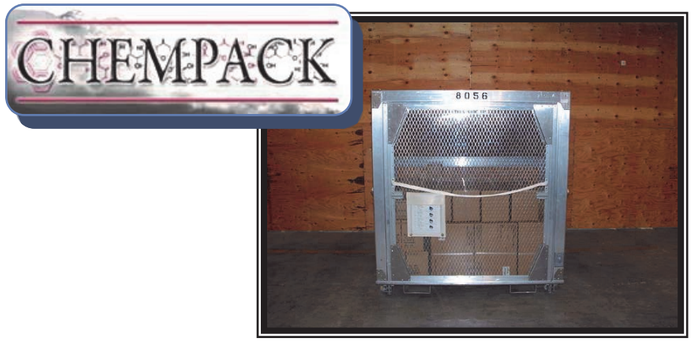
MEDDRUN is a Michigan asset designed to supplement local and regional pharmaceutical and medical supplies in the event of a chemical, biological, or other emergency resulting in mass casualties. MEDDRUN resources may deal with a situation, or in a very large scale event, may serve as a stopgap measure until Strategic National Stockpile (SNS) assets arrive. MEDDRUN is deployable within one hour or less to 90% of the state of Michigan.

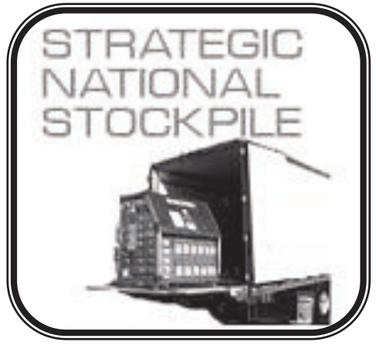
CHEMPACK is a federal resource, managed by the State of Michigan that provides a supplemental source of antidotes suitable to treat large-scale exposure to nerve agents or organophosphate pesticides. It is located throughout the state of Michigan.

The SNS is a Centers for Disease Control and Prevention (CDC) asset which is large quantities of pharmaceuticals and medical supplies to protect American citizens if there is a public health emergency (such as a terrorist attack, influenza outbreak, etc.) severe enough to cause local, regional and state supplies to deplete quickly. When local, regional, and state medical resources are depleted, then a request can be made for the National Strategic National Stockpile (SNS).

To learn more about MEDDRUN, CHEMPACK, and SNS login to MI-TRAIN (http://mi.train.org) and search for course # 1031785. If you have questions about the course, please contact Kerry Chamberlain at chamberlaink2@michigan.gov







In The Works: Molecular *Salmonella* Serotyping

Author: Beth Holben, MT (ASCP), Microbiologist, Microbiology Section

Salmonella infections are one of the leading bacterial causes of gastrointestinal illness in the United States. Because of health concerns, cost burden, and epidemiological importance associated with *Salmonella* infections, regulations require reporting of *Salmonella* serotypes for all detected cases.

At the Michigan Department of Health and Human Services Bureau of Laboratories (MDHHS BOL), the current method for *Salmonella* serotyping is the conventional or manual method, which is done by slide and tube agglutination. The agglutination reaction is based on the immunological reactivity of two surface structures of the *Salmonella* cell, the "O" or somatic antigen and the "H" or flagellar antigen, which can have several phases. There are 46 distinct O serogroups and 114 H antigens in various combinations to define the over 2,500 characterized serotypes, designated by the Kauffman-White scheme. This process can be time consuming, subjective, and expensive.

A molecular serotyping method capable of completely serotyping 85% of the top 100 serotypes most commonly encountered in testing laboratories has been developed by the CDC. This assay will also provide partial results for most other serovars. Our laboratory is currently working on a validation for this method, utilizing the Luminex® xMAP® *Salmonella* Serotyping Assay and the Bio-Plex 200 System. The advantages of using a molecular approach include the ability to serotype problematic isolates, eliminate the need for additional testing to separate the flagellar antigens (decreases turnaround time), improved reliability, eliminate subjectivity, and high throughput. With molecular serotyping up to 32 samples can be analyzed on one 96 well plate; compared to conventional serotyping where each sample is tested individually. The testing component of the validation for this new molecular technology will be completed in the next couple of months.

The Bureau of Laboratories Webpage Content Updates

Attention all laboratory system partners. The Bureau of Laboratories is in the process of updating our laboratory web page contents. Please check our web page often for updates to forms, instructions, and other posted materials.

Remember to use our new laboratory webpage shortcut. Thank you.

http://www.michigan.gov/mdhhslab.

Please save this address as one of your internet favorites.

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